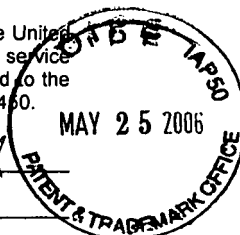


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*Shelia Alexander*  
Shelia Alexander  
Date of Signature \_\_\_\_\_

May 26, 2006



**PATENT**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: *Petitte et al.*

Group Art Unit: 1632

**Serial No.: 09/757,054**

Examiner: Wilson, Michael C.

Filed: January 8, 2001

Docket No.: 297/93/2

Confirmation No.: 7757

For: METHOD OF PRODUCING AN UNDIFFERENTIATED AVIAN CELL CULTURE  
USING AVIAN PRIMORDIAL GERM CELLS

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APPLICANTS' STATEMENT IN SUPPORT OF THE  
PRE-APPEAL BRIEF REQUEST FOR REVIEW

INTRODUCTION

Claims 44, 47, 48, 51-54, and 56-58 are pending in U.S. Patent Application Serial No. 09/757,054 (hereinafter "the '055 Application"). All pending claims have been rejected on one or more bases as presented in the Final Official Action dated December 30, 2005 (hereinafter "the Final Official Action"). Applicants respectfully submit that none of the rejections presented in the Final Official Action are supported by the assertions made by the United States Patent and Trademark Office (hereinafter "the Patent Office") and/or by the references cited in the Final Official Action, as set forth in more detail hereinbelow.

I. The New Matter Rejection of Claims 53 and 54

Claims 53 and 54 have been rejected under 35 U.S.C. § 112, first paragraph, upon the contention that the specification did not contemplate maintaining the ES cell phenotype for one or two months. According to the Patent Office, the specification discloses that the avian embryo cells can be cultured for at least one or two months, but this does not imply that the ES cell phenotype can be maintained for one or two months (see Official Action dated April 6, 2005, at page 3).

In response to this assertion, applicants contend, and have contended, that the strong presumption of adequate written description set forth in the Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶1, "Written Description" Requirement (66 Federal Register 1099, 2001; hereinafter the "Guidelines") cannot be overcome merely by offering an alternative interpretation of a passage in the specification.

Rather, the Guidelines require that the Examiner introduce sufficient evidence or technical reasoning to shift the burden of going forward with contrary evidence to the applicant" (Guidelines at page 1100; emphasis added).

In the Final Official Action, the Patent Office asserted that "the absence of maintaining the stem cell phenotype for at least one or two months as claimed is adequate 'evidence or technical reasoning' that applicants did not disclose the subject matter at the time of filing" (see Final Official Action at pages 2-3). It appears from this statement that the Patent Office is asserting that the specification did not disclose that the ES cell phenotype was maintained for one or two months, and thus because it did not, the "evidence or technical reasoning" was provided *per se*. It is thus believed that the argument advanced by the Patent Office, which is circular in nature, does not support the rejection, and certainly cannot be used to overcome a strong presumption of the adequacy of the written description. Additionally, the Conference Panel's attention is also directed to the arguments presented in Amendment F, pages 6-8, as well as those presented in Amendment E (see pages 5-7) and Amendment D (see pages 14-15).

Summarily, applicants respectfully submit that the instant application is directed to sustained cultures of undifferentiated avian cells expressing an ES cell phenotype. This is believed to be clearly disclosed in the Summary beginning at page 3, line 18, of the present U.S. patent application as filed. Applicants further respectfully submit that there would have been no point to disclosing that the cultures can be sustained for at least one or two months if during this period the cultures no longer maintained their status as sustained cultures of undifferentiated avian cells expressing an ES cell phenotype. As a result, the specification when taken as a whole discloses that the ES cell phenotype is maintained for at least one or two months, and the instant rejection should be withdrawn.

## II. The Enablement Rejection

Claims 44, 47, 48, 51-54, and 56-58 have been rejected under the enablement provision of 35 U.S.C. § 112, first paragraph. According to the Patent Office, the specification does not enable a culture wherein the ES cells are maintained for one or two months. This assertion appears to be based at least in part on the Simkiss, Petitte, and Ponce de Leon references of record (see pages 3-4 of the Final Official Action).

Applicants respectfully submit that these references do not support the instant rejection. Applicants respectfully submit that at best each of these references teaches long term culture of PGCs, and the present claims are not directed to long term culture of PGCs

but to the culture of an undifferentiated derivative of a PGC that has an ES cell phenotype. The Conference Panel's attention is directed to pages 9-10 of Amendment F, in which applicants discuss the differences between the cell types cultured in the cited references and the cells cultured in the instant claims.

Applicants respectfully reiterate that the culture conditions required for long term culture of PGCs are not relevant to the culture conditions required for the instantly claimed cultures, and in fact the culture conditions for the instantly claimed cultures would have to be different or the PGCs isolated from the chicken embryo would remain PGCs in the culture. This does not happen, however. Therefore, it is believed that the specific growth factor requirements for long term PGC culture do not inform one of ordinary skill in the art about the culture conditions for the instantly claimed cultures. Rather, applicants respectfully submit that the specification as filed provides a complete teaching that allows one of ordinary skill in the art to make and use the instant cultures, and thus claims 44, 47, 48, 51-54, and 56-58 comply with the enablement requirement of 35 U.S.C. § 112, first paragraph. Therefore, this rejection should be withdrawn.

*III. The Rejections under 35 U.S.C. § 112, Second Paragraph*

Claims 44, 47, 48, 51-54, and 56-58 have been rejected upon the contention that these claims are indefinite for the reasons set forth on pages 6-11 of the Final Official Action. The phrases at issue are as follows: (a) "undifferentiated cells expressing an embryonic stem cell phenotype"; and (b) "large nucleus, prominent nucleolus, and little cytoplasm".

The Patent Office's assertions are believed to be rebutted on pages 10-14 of Amendment F. Additionally, with respect to phrase (a), applicants respectfully submit that the specification specifically defines this phrase, and co-inventor Petite's issued U.S. Patent Nos. 5,340,740; 5,656,479; 5,830,510; and 6,333,192 all employ this phrase in the claims. Given that the Patent Office has already taken the position that this phrase is not indefinite on these four specific occasions, including in the prosecution of the '192 Patent, which contains the exact same specification as the instant application, the Patent Office has provided no reasonable explanation as to why a phrase that was not considered ambiguous in U.S. Patent Application Serial No. 09/370,708 (which issued as the '192 Patent) should now be considered ambiguous in a Continuation application.

With respect to phrase (b), applicants have argued that this is an art-recognized morphological description of ES cells and ES-like cells. Applicants have also set forth how

PGCs differ in their morphology. The Conference Panel's attention is directed to the Declaration Pursuant to 37 C.F.R. § 1.132 filed October 6, 2005.

And finally, the Patent Office asserts that it remains unclear how PGCs isolated from an embryo later than stage 14 are distinguished from PGCs isolated from a stage X or a stage 14 embryo. This assertion is addressed on pages 13-14 of Amendment F, and relates at least in part to changes that were believed to result from the migration and localization of PGCs in the gonad and/or genital ridge of the later than stage 14 chicken embryo.

Accordingly, applicants respectfully submit that when viewed in the context of the instant specification and with the knowledge of the skilled artisan, the phrases at issue are not ambiguous and thus the claims are believed to comply with the second paragraph of 35 U.S.C. § 112.

#### IV. The Art-based Rejections

Claims 44, 47, 48, 51-54, and 56-58 have been rejected under one or more sections of 35 U.S.C. § 102 upon the contention that the claims are anticipated by one or more of Chang 1995; Chang 1997; U.S. Patent No. 5,340,740; U.S. Patent No. 5,656,479; and/or U.S. Patent No. 5,830,510 (collectively "the Petite Patents"; each of record). Claims 44, 47, 48, 51-54, and 56-58 have also been rejected under 35 U.S.C. § 103(a) upon the contention that the claims are obvious over U.S. Patent No. 6,156,569 in view of Chang 1995 of record for the reasons set forth on pages 15-17. And finally, claims 44, 47, 48, 51-54, and 56-58 have been rejected under the doctrine of obviousness-type double patenting over claims 1 and 8-10 of U.S. Patent No. 5,340,740 in view of the disclosure of the '740 Patent and Chang 1995 of record.

Applicants respectfully submit that these references do not support a rejection of any of the claims under either 35 U.S.C. § 102 or 35 U.S.C. § 103 for the reasons set forth on pages 14-25 of Amendment F. Summarily, applicants respectfully submit that Chang 1995 and Chang 1997 disclose cultures of PGCs, and the instant claims are not directed to PGCs *per se* but to derivatives of PGCs that differ morphologically and functionally from PGCs. Thus, neither Chang 1995 nor Chang 1997 supports the instant rejections.

With respect to the Petite Patents, none of these patents is believed to disclose cultures comprising "chicken primordial germ cells and chicken stromal cells, wherein the chicken primordial germ cells and stromal cells are isolated together from the embryonic genital ridge or gonad from a chicken embryo". The Petite Patents relate to cells isolated

from Stage X chicken embryos, and stage X embryos do not have an embryonic genital ridge or gonad.

Turning now to the rejections under 35 U.S.C. § 103, U.S. Patent No. 6,156,569 and Chang 1995 both disclose culturing of PGCs *per se*, and thus cannot be read to disclose or suggest a sustained culture of undifferentiated chicken cells that (i) are derived from the chicken primordial germ cells isolated from the chicken embryo; (ii) are smaller than the chicken primordial germ cells; and (iii) form one or more colonies of tightly packed undifferentiated chicken cells expressing an embryonic stem cell phenotype. The Conference Panel's attention is directed to the Declaration Pursuant to 37 C.F.R. § 1.132 filed October 6, 2005, which clearly sets forth how these cells of the claimed cultures differ from PGCs.

And finally, with respect to the obviousness-type double patenting rejections, applicants have presented evidence that one of ordinary skill in the art would not have believed that PGCs isolated from a later than stage 14 chicken embryo would have been able to form the claimed cultures (see Amendment F at pages 20-25). Given that one of ordinary skill in the art would have believed these cells to be committed to terminal differentiation once they arrive in the gonad, as of the priority date of the instant application there would have been no motivation for one of ordinary skill in the art to have attempted to create undifferentiated cultures from these cells, nor would there have been a reasonable expectation of success.

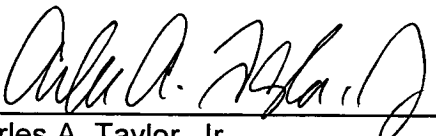
Therefore, the instantly claimed sustained cultures represent an unexpected discovery, and the Patent Office's assertions in support of this rejection are believed to be addressed. Accordingly, applicants respectfully submit that claims 44, 47, 48, 51-54, and 56-58 are in condition for allowance. Applicants respectfully request a Notice of Allowance for claims 44, 47, 48, 51-54, and 56-58.

Respectfully submitted,

JENKINS, WILSON, TAYLOR & HUNT, P.A.

Date: May 26, 2006

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